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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,109	08/20/2003	Jean-Marie Stutzmann	USST98048USDIV1	6531
5487	7590	08/09/2005	EXAMINER	
ROSS J. OEHLER AVENTIS PHARMACEUTICALS INC. ROUTE 202-206 MAIL CODE: D303A BRIDGEWATER, NJ 08807			KRISHNAN, GANAPATHY	
			ART UNIT	PAPER NUMBER
			1623	
DATE MAILED: 08/09/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/644,109		STUTZMANN ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Ganapathy Krishnan		1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 20-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

The amendment filed 6/1/2005 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 1-19 have been canceled.
2. New Claims 20-35 have been added.
3. Remarks drawn to objections and rejections under double patenting, 35 USC 102 and 103.

Claims 20-35 are pending in the case.

The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

#### ***Claim Objections***

The objection to claim 2 has been rendered moot by cancellation of the claim.

#### ***Double Patenting***

The rejection of claims 1-7 and 9-19 under 35 USC 101 as claiming the same invention as that of claims 1-7 and 9-19 of copending Application No. 10/644150 and the obviousness-type double patenting of claims 1-7 and 9-19 as being unpatentable over claim 34 of U.S. Patent No. 6,608,042 ('042 patent) have been overcome by amendment.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating motoneuron diseases, does not reasonably provide enablement for prevention of motoneuron diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

- (A) The breadth of the claims
- (B) The state of the prior art
- (C) The level of one of ordinary skill
- (D) The level of predictability in the art
- (E) The amount of direction provided by the inventor
- (F) The existence of working examples
- (G) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

**The breadth of the claims**

Claims 20-35 are drawn to a method for preventing a motoneuron disease in a patient comprising administering an effective amount of low molecular weight heparin, and heparin with specific molecular weights. The scope of the claim is seen to include the administration of the

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said compound to a healthy patient, and subsequent exposure to conditions that would cause the motoneuron disease, wherein the said compound prevents the said exposure from manifesting itself in said patient so exposed.

**The state of the prior art**

The examiner notes that the art cited by the applicants mentions methods for preparing heparins and use of the same in treating thrombosis. Snow et al (WO 91/06303) drawn to glycosaminoglycans and proteoglycans, disclose the use of these compounds for the regeneration/treatment of neurons damaged by disorders like amyotrophic lateral sclerosis. Von Arnim (WO 94/18988) teaches the treatment of multiple sclerosis using low molecular weight heparins. However, there is no disclosure of potential motoneuron disease preventive activity of the compound seen in the prior art. The prior art appears to be silent with regard to preventive procedures recognized by skilled artisans in the field.

**The level of one of ordinary skill**

The skilled artisan in this field is that of an MD for chemotherapeutic administration and/or a Ph.D. skilled in the development of chemotherapeutics.

**The level of predictability in the art**

The examiner acknowledges the probability and predictability that administration of the said compounds may have a reasonable expectation of success for preventing the said disease. There is not seen sufficient data to substantiate the assertion that the said disease may be prevented by the use of the compound as instantly claimed.

**The amount of direction provided by the inventor**

The instant specification is not seen to provide enough guidance that would allow a skilled artisan to extrapolate from the disclosure and the examples provided to enable the use of the active agents to prevent motoneuron disease. The specification also fails to direct the skilled artisan in correlative prior art procedures which might provide the basis for an advance in treating motoneuron disease which induces prevention of the said disease.

**The existence of working examples**

The working examples set forth in the instant specification are drawn to data involving cells in vitro. The skilled artisan in this field would not extrapolate the preventive efficacy of the compound claimed or the use of the same in preventive methods from just this example provided. The disclosure does not show the prevention of motoneuron disease. However, it is seen to show the effect of the active agents.

**The quantity of experimentation needed to make or use the invention based on the content of the disclosure**

Indeed, in view of the information set forth, the instant disclosure is not seen to be sufficient to enable the prevention of motoneuron disease with the compound set forth in the claims. A skilled artisan would not extrapolate the preventive efficacy from the results disclosed in the examples, set forth in the instant specifications.

***Claim Rejections - 35 USC § 102***

The rejection of claims 1, 2 and 12 has been rendered moot by cancellation.

***Claim Rejections - 35 USC § 103***

The rejection of claims 1-7 and 9-19 has been rendered moot by cancellation.

***Conclusion***

Claims 20-35 are rejected

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

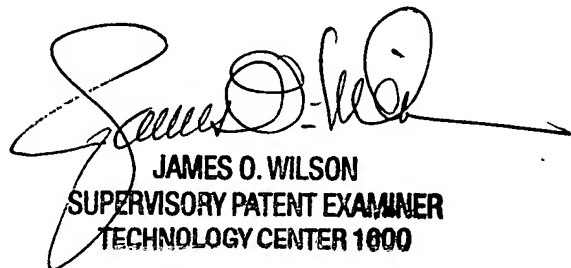
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK



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